433.440: continued

(2) For information on reimbursable services for recipients of the Emergency Aid to the Elderly, Disabled and Children Program (category of assistance 04), see 130 CMR 450.111.

(B) Service Limitations. The Division will pay for legend drugs that are approved by the U.S. Food and Drug Administration, except as outlined below. The Division will pay for the nonlegend drugs listed in the Nonlegend Drug List; this list is sent to pharmacies by the Division. In order to be reimbursable, legend and nonlegend drugs must be manufactured by companies that have signed rebate agreements with the U.S. Secretary of Health and Human Services pursuant to Section 4401 of the Omnibus Budget Reconciliation Act of 1990. A list of the companies that have signed rebate agreements is sent to pharmacies by the Division.

(1) Interchangeable Drug Products. For drugs listed in the Massachusetts List of Interchangeable Drugs (105 CMR 720.000) or any supplement thereof, the Division will pay no more than the maximum allowable cost (MAC) or Massachusetts maximum allowable cost (MMAC) unless:

(a) the prescriber has requested and received prior authorization from the Division for a nongeneric multiple-source drug (see 130 CMR 433.408). With the prior authorization request to the Division, the prescriber must submit written supporting documentation stating the reasons the recipient's medical condition requires the nongeneric drug; or

(b) the prescriber has written on the face of the prescription in his own handwriting the words "brand name medically necessary" under the words "no substitution" in a manner consistent with applicable state law. These words must be written out in full and may not be abbreviated.

(2) Minor Tranquilizers.

(a) The Division will not pay for any drug that is classified by the Division as a minor tranquilizer, with the following exceptions:

1. generic chlordiazepoxide;
2. generic diazepam;
3. generic lorazepam;
4. generic oxazepam; and
5. generic temazepam.

The list of drugs that the Division has classified as minor tranquilizers is sent to pharmacies by the Division.

(b) The Division will pay for otherwise nonreimbursable minor tranquilizers only if the prescriber has requested and received prior authorization from the Division (see 130 CMR 433.408). With the prior authorization request to the Division, the prescriber must submit written supporting documentation of medical necessity.

(c) In an emergency where a recipient is brought to a hospital emergency room, if the prescriber wishes to prescribe an otherwise nonreimbursable minor tranquilizer for that emergency, the Division will pay a hospital pharmacy for a maximum 14-day supply without prior authorization. The Division will pay only a hospital pharmacy.

(3) Antiulcer Drugs.

(a) The Division pays for a maximum 60-day supply of antiulcer drugs per recipient per six-month period, commencing with the first prescription filled (new or refill) after December 1, 1990. The Division will pay for additional supplies of these drugs within the six-month period only if the prescriber has requested and received prior authorization from the Division (see 130 CMR 433.408). With the prior authorization request to the Division, the prescriber must submit written supporting documentation indicating that the recipient is on maintenance therapy for one of the following conditions or must submit other documentation of medical necessity:

1. duodenal or gastric ulcer;
2. Zollinger-Ellison syndrome; or
3. gastroesophageal reflux disease.

(b) Antiulcer drugs include, but are not limited to, such drugs as histamine (H_2) receptor antagonists and sucralfate.

433.440: continued

(c) Each day's supply of different antiulcer drugs prescribed for use on the same day will be counted as separate days' supplies. For example, a physician has prescribed 100 sucralfate tablets with a dosage of one tablet four times a day (a 25-day supply) and has also prescribed for the same recipient for use on the same days 50 ranitidine tablets with a dosage of one tablet twice a day (a 25-day supply). For purposes of calculating the days' supply of antiulcer drugs, the days' supply of each of the dispensed drugs is added together. Therefore, this recipient would now have used a 50-day supply of antiulcer drugs.

(4) Potassium Supplements. The Division pays for those potassium supplements listed in Appendix I of the *Pharmacy Manual*. This list is sent to pharmacies by the Division. The Division will also pay for a potassium supplement not listed in Appendix I if the prescriber has requested and received prior authorization from the Division (see 130 CMR 433.408). With the prior authorization request to the Division, the prescriber must submit written supporting documentation of the medical necessity of the drug, including the reason why none listed in Appendix I would suffice.

(5) Topical Acne Drugs. The Division does not pay for topical acne products unless the prescriber has requested and received prior authorization from the Division (see 130 CMR 433.408). The Division will grant prior authorization only for cases of severe acne. With the prior authorization request to the Division, the prescriber must submit written supporting documentation of medical necessity.

(6) Cosmetic Drugs. The Division does not pay for drugs used for cosmetic purposes or for hair growth.

(7) Nicorette. The Division does not pay for Nicorette or any other drug used for smoking cessation.

(8) Methyl Phenidate (Ritalin) and Amphetamines. The Division does not pay for methyl phenidate (Ritalin), amphetamines (including amphetamines in combination), or any other drugs when they are used for control of the appetite. When prescribed for the treatment of hyperkinesis, however, such drugs are reimbursable without prior authorization until the recipient reaches his 17th birthday. All other uses of amphetamines require prior authorization (see 130 CMR 433.408).

(9) Nonlegend Vitamins. The Division pays for nonlegend vitamins only if they are included in the Nonlegend Drug List and then only when they are dispensed to infants or children until they reach their third birthday or to pregnant women. General multiple vitamins NF (National Formulary) in a unit of 100 are reimbursable without age restriction.

(10) Vitamin B12. The Division pays for vitamin B12 only for a recipient having a diagnosis of pernicious anemia. The medical record must document the recipient's medical history as well as the physical and laboratory findings that support such a diagnosis. An office, home, or hospital outpatient visit for the sole purpose of administering vitamin B12 is reimbursable only if the B12 therapy is reimbursable.

(11) Fluorides. The Division does not pay for plain fluorides for recipients aged 12 and over unless the prescriber has requested and received prior authorization from the Division (see 130 CMR 433.408). With the prior authorization request to the Division, the prescriber must submit written supporting documentation of medical necessity.

(12) Iron. The Division pays only for those iron preparations included in the Nonlegend Drug List.

(13) Persantine. The Division does not pay for Persantine or any other dipyridamole for which the U.S. Food and Drug Administration has granted the labeling and use indication described in this subsection unless the prescriber has requested and received prior authorization from the Division (see 130 CMR 433.408). The Division will grant prior authorization only for an indication approved by the U.S. Food and Drug Administration (currently as an adjunct to coumarin anticoagulants in the prevention of postoperative thromboembolic complications of cardiac-valve replacement).

433.440: continued

(14) Less-Than-Effective Drugs. The Division does not pay for drug products (including identical, similar, or related drug products) that the U.S. Food and Drug Administration has proposed, in a notice of opportunity for hearing (NOOH), to withdraw from the market because they lack substantial evidence of effectiveness for all labeled indications. (Examples of drug products affected by 130 CMR 433.440 are listed in Appendix H of the *Physician Manual.*)

(15) Immunizing Biologicals and Tubercular Drugs.

(a) Immunizing biologicals and tubercular (TB) drugs available free of charge through local boards of public health or through the Massachusetts Department of Public Health are not reimbursable. If the recipient has a prescription, however, the Division will pay for the following drugs for a nonambulatory recipient who cannot attend one of the Department of Public Health clinics: Isoniazid, Myambutal, and P.A.S. All other such drugs require prior authorization (see 130 CMR 433.408).

(b) 130 CMR 433.440(B)(15)(a) notwithstanding, the Division does pay for pneumococcal vaccine when dispensed to a noninstitutionalized recipient.

(16) Allergy Serums. For regulations concerning payment for allergy serums, see 130 CMR 433.427.

(17) Antacids. The Division pays only for antacids dispensed to a noninstitutionalized recipient. Reimbursable antacids include those legend drugs manufactured by companies that have signed rebate agreements with the U.S. Secretary of Health and Human Services pursuant to Section 4401 of the Omnibus Budget Reconciliation Act of 1990, and only those nonlegend drugs listed in Appendix F of the *Pharmacy Manual* that are manufactured by companies that have signed rebate agreements. A list of the companies that have signed rebate agreements is sent to pharmacies by the Division. The Division pays for other antacids only if the prescriber has requested and received prior authorization from the Division (see 130 CMR 433.408). With the prior authorization request to the Division, the prescriber must submit written supporting documentation of medical necessity.

(18) Laxatives and Stool Softeners. The Division does not pay for laxatives or stool softeners unless the prescriber has requested and received prior-authorization from the Division (see 130 CMR 433.408). With the prior-authorization request to the Division, the prescriber must submit written supporting documentation of medical necessity.

(19) Cough and Cold Preparations. The Division does not pay for legend or nonlegend preparations that contain a decongestant, antitussive, or expectorant as a major ingredient, or any drug used for the symptomatic relief of coughs and colds, when they are dispensed to a noninstitutionalized recipient.

(20) Propoxyphene. The Division does not pay for any drug product that contains propoxyphene, except

(a) propoxyphene hydrochloride 32 mg; and

(b) propoxyphene hydrochloride 65 mg, unless the prescriber has requested and received prior-authorization from the Division (see 130 CMR 433.408). With the prior-authorization request to the Division, the prescriber must submit written supporting documentation of medical necessity.

(21) Hexachlorophene Preparations. The Division does not pay for preparations containing hexachlorophene, U.S.P. as the major active ingredient unless the prescriber has requested and received prior-authorization from the Division (see 130 CMR 433.408). With the prior-authorization request to the Division, the prescriber must submit written supporting documentation of medical necessity.

(22) Sex-Reassignment Hormone Therapy. The Division does not pay for drugs related to sex-reassignment surgery. This specifically includes, but is not limited to, presurgery and postsurgery hormone therapy. Notwithstanding the preceding sentence, the Division will continue to pay for post-sex-reassignment surgery hormone therapy for which it had been paying immediately prior to May 15, 1993.

(23) Unit-Dose Distribution System. The Division does not pay any additional fees for dispensing drugs in unit dose.

(24) Fertility Drugs. The Division does not pay for any drugs used to treat male or female infertility (specifically including, but not limited to, A.P.L., chorionic gonadotropins, Clomid, clomiphines, hCg, menotropins, Milphene, Pergonal, Pregnyl, Profasi, Profasi HP, and Serophene).

433.440: continued

(C) Payment. Drugs dispensed in the office are reimbursable at the physician's actual acquisition cost if this cost is more than $1.00. Claims for dispensing drugs must include the name of the drug or biological, the strength, and the dosage, and must have a copy of the invoice showing the actual acquisition cost attached to the claim form. Claims without this information will be denied. Payment for drugs may be claimed in addition to an office visit.

433.441: Medical Supplies: Dispensing

Medical supplies dispensed in the office are reimbursable at the physician's acquisition cost if this cost is more than $1.00. Claims for dispensing medical supplies must include a complete description of the item, the quantity dispensed, and whether the item is standard or custom-made, and must have a copy of the invoice showing the acquisition cost attached to the claim form. Payment for medical supplies may be claimed in addition to an office visit.

433.451: Surgery Services: Introduction

(A) Provider Eligibility. A physician will be paid for surgery only if the physician is scrubbed and present in the operating room during the major portion of the operation. (See 130 CMR 433.421(D)(1) for the single exception to this requirement.)

(B) Reimbursable Services. All services listed in Subchapter 6 of the *Physician Manual* are reimbursable subject to Division regulations (130 CMR) and the following limitations.

(1) Any experimental, unproven, cosmetic or otherwise medically unnecessary procedure or treatment is not reimbursable. This specifically includes, but is not limited to, sex-reassignment surgery, thyroid cartilage reduction surgery, and any other related surgeries.

(2) The treatment of male or female infertility (including, but not limited to, laboratory tests, drugs, and procedures associated with such treatment) is not reimbursable.

(3) Reconstructive surgery is reimbursable only when determined by the Division pursuant to a request for prior authorization to be medically necessary to correct, repair, or ameliorate the physical effects of physical disease or defect, or traumatic injury.

(4) Abortion and sterilization procedures are reimbursable subject to specific Division regulations (*see* 130 CMR 433.455 through 433.458).

(5) Hysterectomies are reimbursable subject to specific Division regulations (*see* 130 CMR 433.459).

433.452: Surgery Services: Payment

The maximum allowable fees for the surgery services listed in Subchapter 6 of the *Physician Manual* apply to surgery procedures performed in any setting. The Division will pay a physician for either a visit or a treatment/procedure, whichever commands a higher fee; the Division will not pay for both a visit and a treatment/procedure provided to a recipient on the same day when they are performed in the same location. All maximum allowable fees for surgery procedures include payment for the initial application of casts, traction devices, or similar appliances.

(A) Obstetrics.

(1) Obstetric fees include payment for procedures performed and care given to a recipient in a hospital or at home. However, the Division will give individual consideration to a claim for extended obstetric preoperative or postoperative care due to unusual circumstances, if the physician requests it and attaches adequate medical documentation to the claim form.

(2) The Division offers the following two methods of reimbursement for obstetric services.

(a) Fee for Service. The fee-for-service method requires submission of claims for services as they are performed. Prenatal and postpartum visits are billed by using the applicable adult or pediatric office visit codes. Fee for service is always available for reimbursable obstetric services.

433.452: continued

(b) Global Fee. The global fee method offers two options, the standard global fee and the enhanced global fee (see 130 CMR 433.422 and 433.423). Both are available only when the conditions in 130 CMR 433.421 are met.

(B) Inpatient Services.

(1) For surgery procedures performed on an inpatient in a licensed hospital, the fees include payment for preoperative diagnosis and postoperative care during the period of hospitalization.

(2) The Division will give individual consideration to a claim for extended preoperative or postoperative care due to unusual circumstances, if the physician requests it and attaches adequate medical documentation to the claim form.

(3) A physician who performs an inpatient surgery procedure but does not provide the postoperative care will be paid 85% of the maximum allowable fee. The physician providing the postoperative care will be paid according to the applicable office, hospital, or home visit fee.

(C) Surgical Assistants. No payment will be made to a surgical assistant for a procedure with an allowable fee of less than $63.75. For other procedures, a surgical assistant will be paid 15% of the maximum allowable fee, with a minimum payment of $20.00.

(D) "Team" Surgery. When two or more physicians participate in an operative procedure, and when each physician contributes an expertise because of specialty training and performs a discrete portion of the operative procedure, the physician who is the consulting surgeon will be paid on an individual consideration basis. To claim payment, each consulting surgeon must indicate "team" surgery on the claim form he or she submits and must attach to it a complete operative report, including a description of each consulting surgeon's role. The physician who is the primary surgeon (surgeon of record) should bill in the usual manner.

(E) Multiple Procedures. In most circumstances, the Division will pay for only one operative procedure in a single operative session. For example, it is inappropriate to request payment for both an exploratory laparotomy and an appendectomy, or for both an arthrotomy and a meniscectomy. When two definitive procedures are performed during the same operative session, and neither procedure is designated "I.P." (for independent procedure) (*see* 130 CMR 433.452(F)), the full maximum allowable fee will be paid for one procedure, and 50% of the maximum allowable fee will be paid for each additional procedure.

(F) Independent Procedures. A number of surgery procedures are designated "I.P." in the service descriptions in Subchapter 6 of the *Physician Manual*. I.P. is an abbreviation for independent procedure. An independent procedure is reimbursable only when no other procedure is performed during the same operative session, unless one of the exceptions in 130 CMR 433.452(F)(1) through (3) applies.

(1) When during the same operative session an additional surgery procedure performed by the same physician is designated "I.P." and requires an unrelated operative incision, the full maximum allowable fee will be paid for the procedure with the largest fee, and 50% of the maximum allowable fee will be paid for each additional procedure, unless otherwise provided herein. In the event that two or more procedures are scheduled at the largest amount, the full maximum allowable fee will be paid for only one of the procedures, and 50% of the maximum allowable fee will be paid for each additional procedure, unless otherwise provided herein.

(2) When during the same operative session one or more of the surgery procedures performed by the same physician is designated "I.P." and does not require an unrelated operative incision, the maximum allowable fee will be paid for the procedure commanding the largest fee, and no payment will be made for any other procedure.

(3) When during the same operative session all of the surgery procedures performed by the same physician are designated "I.P." and one or more requires an unrelated operative incision, payment shall be determined on the basis of individual consideration.

433.454: Anesthesia Services

(A) Payment.

(1) Payment for anesthesia services is determined by a system of base anesthesia units and time units. The surgery and medical service codes and descriptions list the number of base anesthesia units for each service. To this number, the Division adds one additional unit for each quarter hour or fraction thereof, provided such fraction equals or exceeds five minutes, according to the time-unit information entered on the claims form. If no base anesthesia units are listed for a service, payment is determined by time units alone. The time-unit period begins at the moment of the actual administration of the anesthetic agent and ends when the anesthetic procedure terminates. (*See* the instructions in Subchapter 5 of the *Physician Manuel* for completing Block 19 of the claim form.)

(2) The base anethesia units listed with the service codes and descriptions are the maximum number of base units used to determine the fee. The number of base units is the same, regardless of the type of anesthesia administered, including acupuncture (*see* 130 CMR 433.454(C))

(3) When anesthesia is administered for multiple surgery procedures, only the base anesthesia units for that procedure with the largest number of units will be applied in computing the maximum allowable fee.

(B) Services Provided by a Nurse-Anesthetist. Anesthesia services provided by a nurse-anesthetist are reimbursable only if the nurse-anesthetist meets the following conditions:

(1) is authorized by law to perform the services for which payment is sought;

(2) is a full-time employee of the physician and is not a salaried employee of the hospital; and

(3) performs the services under the direct and continuous supervision of the physician.

The physician must be in the operating suite and responsible for no more than two operating rooms. Availability of the physician by telephone does not constitute direct and continuous supervision.

(C) Acupuncture as an Anesthetic. Evidence indicates that acupuncture may be safely and effectively used in lieu of a general anesthetic. The Division will pay for acupuncture only as a substitute for conventional surgical anesthesia.

433.455: Abortion Services

(A) Eligible Recipients. The Division pays for abortion services provided to Medical Assistance recipients (categories of assistance 00, 01, 02, 03, 05, 06, 07, and 08). For information on reimbursable services for recipients of the Emergency Aid to the Elderly, Disabled and Children Program (category of assistance 04), see 130 CMR 450.111.

(B) Reimbursable Services.

(1) The Division will pay for an abortion service if both of the following conditions are met:

(a) the abortion is a medically necessary abortion, or the abortion is performed upon a victim of rape or incest when such rape or incest has been reported to a law enforcement agency or public health service within 60 days of the incident; and

(b) the abortion is performed in accordance with M.G.L. c. 112, §§ 12K through 12U, except as provided under 130 CMR 433.455(D)(2).

(2) For the purposes of 130 CMR 433.455, a medically necessary abortion is one that, according to the medical judgment of a licensed physician, is necessary in light of all factors affecting the woman's health.

(3) Unless otherwise indicated, all abortions referred to in 130 CMR 433.455 are payable abortions as defined in 130 CMR 433.455(B)(1) and (2).

(C) Assurance of Recipient Rights. No provider shall use any form of coercion in the provision of abortion services. Neither the Division nor any provider, nor any agent or employee of a provider, shall mislead any recipient into believing that a decision to have or not to have an abortion will adversely affect the recipient's entitlement to benefits or services for which the recipient would otherwise be eligible. The Division has strict requirements for confidentiality of recipient records for abortion services as well as for all other medical services reimbursable under the Medical Assistance Program.

433.455: continued

(D) Locations in Which Abortions May Be Performed. Abortions must be performed in compliance with the following.

(1) First-Trimester Abortion. A first-trimester abortion must be performed by a licensed and qualified physician in a clinic licensed by the Department of Public Health to perform surgical services, or in a hospital licensed by the Department of Public Health to provide medical/surgical services.

(2) Second-Trimester Abortion. A second-trimester abortion must be performed by a licensed and qualified physician in a hospital licensed by the Department of Public Health to provide medical surgical/services; provided, however, that up to and including the 18th week of pregnancy, a second-trimester abortion may be performed in a clinic that meets the requirements of 130 CMR 433.455(D)(1) where the attending physician certifies in the medical record that, in his or her professional judgment, a nonhospital setting is medically appropriate in the specific case.

(3) Third-Trimester Abortion. A third-trimester abortion must be performed by a licensed and qualified physician only in a hospital licensed by the Department of Public Health to perform abortions and to provide facilities for obstetric services.

(E) Certification for Payable Abortion Form. All physicians must attach a completed Certification for Payable Abortion (CPA-2) form to each claim form submitted to the Division for a payable abortion. (Instructions for obtaining the Certification for Payable Abortion form are in Subchapter 5 of the *Physician Manual*.) To identify those abortions that meet federal reimbursement standards, specified in 42 CFR 449.100 through 449.109, the Division must secure on the CPA-2 form the certifications described in 130 CMR 433.455(E)(1), (2), and (3), when applicable. For all medically necessary abortions not included in 130 CMR 433.455(E)(1), (2), or (3), the certification described in 130 CMR 433.455(E)(4) is required on the CPA-2 form. The physician must indicate on the CPA-2 form which of the following circumstances is applicable, and must complete that portion of the form with the appropriate signatures.

(1) Life of the Mother Would Be Endangered. The attending physician must certify that, in his professional judgment, the life of the mother would be endangered if the pregnancy were carried to term.

(2) Severe and Long-Lasting Damage to Mother's Physical Health. The attending physician and another physician must each certify that, in his or her professional judgment, severe and long-lasting damage to the mother's physical health would result if the pregnancy were carried to term. At least one of the physicians must also certify that he or she is not an "interested physician", defined herein as one whose income is directly or indirectly affected by the fee paid for the performance of the abortion; or who is the spouse of, or another relative who lives with, a physician whose income is directly or indirectly affected by the fee paid for the performance of the abortion.

(3) Victim of Rape or Incest. The physician is responsible for submitting with the claim form signed documentation from a law enforcement agency or public health service certifying that the person upon whom the procedure was performed was a victim of rape or incest that was reported to the agency or service within 60 days of the incident. (A public health service is defined as either an agency of the federal, state, or local government that provides health or medical services, or a rural health clinic, provided that the agency's principal function is not the performance of abortions.) The documentation must include the date of the incident, the date the report was made, the name and address of the victim and of the person who made the report (if different from the victim), and a statement that the report included the signature of the person who made the report.

(4) Other Medically Necessary Abortions. The attending physician must certify that, in his or her medical judgment, for reasons other than those described in 130 CMR 433.455(E)(1), (2), and (3), the abortion performed was necessary in light of all factors affecting the mother's health.

433.456: Sterilization Services: Introduction

(A) Eligible Recipients. The Division pays for sterilization services provided to Medical Assistance recipients (categories of assistance 00, 01, 02, 03, 05, 06, 07, and 08). For information on reimbursable services for recipients of the Emergency Aid to the Elderly, Disabled and Children Program (category of assistance 04), see 130 CMR 450.111.

(B) Reimbursable Services. The Division will pay for sterilization services provided to a recipient only if all of the following conditions are met:

(1) the recipient has voluntarily given informed consent for the sterilization procedure in the manner and at the time described in 130 CMR 433.457, and such consent is documented in the manner described in 130 CMR 433.458;

(2) the recipient is at least 18 years old at the time consent is obtained; and

(3) the recipient is not mentally incompetent or institutionalized.

(C) Locations in Which Sterilizations May Be Performed.

(1) Male sterilization by vasectomy must be performed by a licensed physician in a physician's office, hospital, or ambulatory sterilization clinic.

(2) Female sterilization by laparoscopy must be performed by a licensed physician either in a hospital or ambulatory sterilization clinic. All other types of female sterilization must be performed by a licensed physician in a hospital.

(D) Assurance of Recipient Rights. No provider shall use any form of coercion in the provision of sterilization services. Neither the Division nor any provider, nor any agent or employee of a provider, shall mislead any recipient into believing that a decision to have or not to have a sterilization will adversely affect the recipient's entitlement to benefits or services for which the recipient would otherwise be eligible. The Division has strict requirements for confidentiality of recipient records for sterilization services as well as for all other medical services reimbursable under the Medical Assistance Program.

433.457: Sterilization Services: Informed Consent Requirements

(A) When Informed Consent Must Be Obtained.

(1) Informed consent for sterilization must be given by the recipient at least 30 days, but not more than 180 days, before the date of the sterilization procedure, except in the case of premature delivery or emergency abdominal surgery. A recipient may be sterilized at the time of a premature delivery or emergency abdominal surgery if at least 72 hours have passed since the recipient gave informed consent for the sterilization. In the case of premature delivery, the informed consent must have been given at least 30 days before the expected date of delivery.

(2) Informed consent for sterilization may not be obtained or given while the recipient requesting sterilization is:

(a) in labor or childbirth;

(b) seeking to obtain or obtaining an abortion; or

(c) under the influence of alcohol or other substances that affect the individual's state of mind.

(B) Obtaining Consent.

(1) The person who obtains consent (for example, a physician, nurse, or counselor) must orally inform the recipient requesting sterilization of all of the following:

(a) advice that the recipient is free to withhold or withdraw consent for the procedure at any time before the sterilization without affecting the right to future care or treatment and without loss of any federal- or state-funded program benefits to which the recipient otherwise might be entitled;

(b) a description of available alternative methods of family planning and birth control;

(c) advice that the sterilization procedure is irreversible;

(d) a thorough explanation of the specific sterilization procedure;

(e) a full description of the discomforts and risks that may accompany or follow the procedure, including an explanation of the type and possible effects of any anesthetic to be used;

433.457: continued

(f) a full description of the benefits or advantages that may be expected as a result of the sterilization; and

(g) advice that the sterilization will not be performed for at least 30 days, except under the circumstances specified in 130 CMR 433.457(A)(1).

(2) The person who obtains consent must also:

(a) offer to answer any questions the recipient may have concerning the sterilization procedure;

(b) give the recipient a copy of the consent form;

(c) make suitable arrangements to ensure that the required information and advice is effectively communicated to any recipient who is blind, deaf, or otherwise handicapped;

(d) provide an interpreter, if the recipient does not understand the language used on the consent form or the language used by the person obtaining consent; and

(e) allow the recipient to have a witness of the recipient's choice present when consent is obtained.

(C) Physician Explanation. Shortly before the performance of the sterilization procedure, the physician performing the procedure must orally inform the recipient of all of the information and advice specified in 130 CMR 433.457(B)(1)(a) through (f). The physician's explanation may be made in the facility upon or after admission for the procedure or in the physician's office shortly before admission, but may not be made at the time of initially obtaining recipient consent. The intent of the physician explanation is to offer the recipient a second explanation of sterilization information to ensure that the recipient fully understands the nature and consequences of sterilization.

433.458: Sterilization Services: Consent Form

(A) Required Consent Form. One of the following Consent for Sterilization forms must be used (the distinction between the two forms is made for federal reimbursement purposes only and will not affect the processing of claims made to the Division for sterilization services):

(1) CS-18 -- for recipients aged 18 through 20; or

(2) CS-21 -- for recipients aged 21 or older.

(Instructions for obtaining the Consent for Sterilization forms are in Subchapter 5 of the *Physician Manual.*)

(B) Completing the Consent Form.

(1) At the time of consent, the consent form must be completed, signed, and dated by:

(a) the recipient;

(b) the interpreter, if one was provided; and

(c) the person obtaining consent. (If the physician is the person obtaining consent, he must sign this statement at the time of consent as well as the physician's statement at a later time.)

(2) After the sterilization procedure is performed, the consent form must be completed, signed, and dated by the physician.

(C) Distributing the Consent Form. The consent form must be completed in triplicate and distributed as follows:

(1) the copy marked "1. Patient" must be given to the recipient at the time of consent;

(2) the copy marked "2. Physician" must be included in the recipient's permanent medical record at the time of admission to the site where the sterilization is performed; and

(3) the copy marked "3. State Agency, Program or Project" must be submitted with the provider's claim to the Division for sterilization services.

(D) Submitting the Consent Form. The physician who performed the sterilization and the hospital, if the sterilization was performed in a hospital, must attach a copy of the completed consent form to their claim forms submitted to the Division for sterilization services. When more than one provider is billing the Division for the same sterilization, photocopies of the completed form may be submitted in lieu of the original.

433.459: Hysterectomy Services

(A) Nonreimbursable Services. The Division will not pay for a hysterectomy provided to a recipient under the following conditions.

(1) The hysterectomy was performed solely for the purpose of sterilizing the recipient.

(2) If there was more than one purpose for the procedure, the hysterectomy would not have been performed but for the purpose of sterilizing the recipient.

(B) The Division will pay for procedures and hospital stays that are subject to the Utilization Management Program only if the applicable requirements of the program as described in 130 CMR 450.207 through 450.211 are satisfied. Appendix I of the *Physician Manual* contains the name, address, and telephone number of the contact organization for the Utilization Management Program and describes the information that must be provided as part of the review process.

(C) Hysterectomy Information Form. The Division will pay for a hysterectomy only when the appropriate section of the Hysterectomy Information (HI-1) form is completed, signed, and dated as specified below.

(1) Prior Acknowledgment. Except under the circumstances specified below, the recipient and her representative, if any, must be informed orally and in writing before the hysterectomy operation that the hysterectomy will make her permanently incapable of reproducing. (Delivery in hand of the Hysterectomy Information (HI-1) form will fulfill the written requirement, but not the oral requirement.) Section (B) of the Hysterectomy Information (HI-1) form must be signed and dated by the recipient or her representative before the operation is performed, as acknowledgment of receipt of this information. Whenever any surgery that includes the possibility of a hysterectomy is scheduled, the recipient must be referred to the Second Opinion Program, informed of the consequences of a hysterectomy, and must sign and date section (B) of the Hysterectomy Information (HI-1) form before surgery.

(2) Prior Sterility. If the recipient is sterile prior to the hysterectomy operation, the physician who performs the operation must so certify, describe the cause of sterility, and sign and date section (C)(1) of the Hysterectomy Information (HI-1) form.

(3) Emergency Surgery. If the hysterectomy is performed in an emergency, under circumstances that immediately threaten the recipient's life, and if the physician determines that obtaining the recipient's prior acknowledgment is not possible, the physician who performs the hysterectomy must so certify, describe the nature of the emergency, and sign and date section (C)(2) of the Hysterectomy Information (HI-1) form. The requirements of the Targeted Procedure Review Component of the Utilization Management Program will be waived if the physician attaches to the claim form a medical report documenting the need to perform the procedure on an emergency basis.

(4) Retroactive Eligibility. If the hysterectomy was performed during the period of a recipient's retroactive eligibility, the physician who performed the hysterectomy must certify that one of the following circumstances existed at the time of the operation:

(a) the woman was informed before the operation that the hysterectomy would make her sterile (the physician must sign and date section (D)(1) of the HI-1 form);

(b) the woman was sterile before the hysterectomy was performed (the physician must sign, date, and describe the cause of sterility in section (D)(2) of the HI-1 form); or

(c) the hysterectomy was performed in an emergency that immediately threatened the woman's life and the physician determined that it was not possible to obtain her prior acknowledgment (the physician must sign, date, and describe the nature of the emergency in section (D)(3) of the HI-1 form).

(D) Submission of the Hysterectomy Information Form. Each provider must attach a copy of the completed Hysterectomy Information (HI-1) form to each claim form submitted to the Division for hysterectomy services. When more than one provider is billing the Division for the same hysterectomy, photocopies of the completed form may be submitted in lieu of the original. (Instructions for obtaining the Hysterectomy Information (HI-1) form are in Subchapter 5 of the *Physician Manual*.)

433.460: The Norplant System of Contraception

(A) Eligible Providers. The Division will pay physicians for the insertion, reinsertion, and removal of the Norplant System of Contraception (Norplant) when they provide the services directly or when the services are provided by a salaried physician, nurse practitioner, nurse midwife, or physician assistant under their supervision. (This is an exception to 130 CMR 450.301.) In order to claim payment for Norplant services, the clinician performing the procedure must be trained by either the manufacturer of Norplant or another clinician who has been trained by the manufacturer.

(B) Reimbursable Services.

(1) Insertion. Payment for the insertion of Norplant is an all-inclusive fee for all services associated with insertion, including counseling and careful patient selection prior to insertion, the Norplant device, the insertion procedure, and one follow-up visit.

(2) Reinsertion. Payment for the reinsertion of Norplant includes removal of the old device, a new device, the insertion procedure, and one follow-up visit.

(3) Removal. The removal of a Norplant device without reinsertion is reimbursed as a separate procedure.

(C) Patient Selection, Counseling Prior to Insertion, and Follow-Up.

(1) In order to prevent premature removal of Norplant, the Division requires careful patient selection and counseling prior to insertion. Counseling must be in accordance with the manufacturer's guidelines, and must include a detailed discussion of potential side effects, contraindications, benefits and risks, and other contraceptive options. Payment for a counseling visit prior to the day of insertion is included in the reimbursement for insertion of Norplant. If the recipient decides not to proceed with the implant after counseling, the provider should bill the counseling as an office visit.

(2) An office visit following insertion is also required as a condition of reimbursement. The visit must include an examination of the insertion site for complications, a review of potential side effects, and follow-up instructions. Payment for the follow-up visit is included in the reimbursement for insertion and reinsertion. If more than one follow-up visit is necessary, the provider must bill each as an office visit.

(3) The provider must make every effort possible to ensure that the recipient returns for the follow-up visit. This shall include, but not be limited to, scheduling the follow-up appointment on the day of insertion, recording the day of the follow-up appointment in the recipient's chart, mailing a reminder notice to the recipient, and reminding the recipient by telephone during the week of the scheduled appointment. The provider must document in the medical record the efforts made to ensure that the recipient returns for the follow-up visit. In order to ensure payment for the procedure, the provider must also document if the recipient fails to return for the follow-up visit.

(D) Service Limitations.

(1) The Division will pay for the insertion and reinsertion of Norplant for female recipients of childbearing age with menstrual histories. The Division will pay for the removal of Norplant for female recipients of all ages.

(2) The Division will pay for the insertion or reinsertion of Norplant only once per recipient per five-year period.

(3) If the recipient has a Norplant device implanted, no other form of contraception should be prescribed, with the exception of condoms. If the Norplant device is removed for any reason, however, the Division will pay for alternative types of contraception.

(E) Payment.

(1) Reimbursement for the services related to Norplant includes both the professional and the technical components involved. Therefore, if a facility bills the Division for services, the individual practitioner who actually performed the service may not bill separately for the same services.

(2) The Division will reimburse all providers for Norplant services at the rate set by the Massachusetts Rate Setting Commission for those services (114.3 CMR 16.00 and 17.00).